Chemical and Material Risk Management Directorate

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Revealing Data Gaps & Needs: Dynamic Risk Management for an Evolving Science

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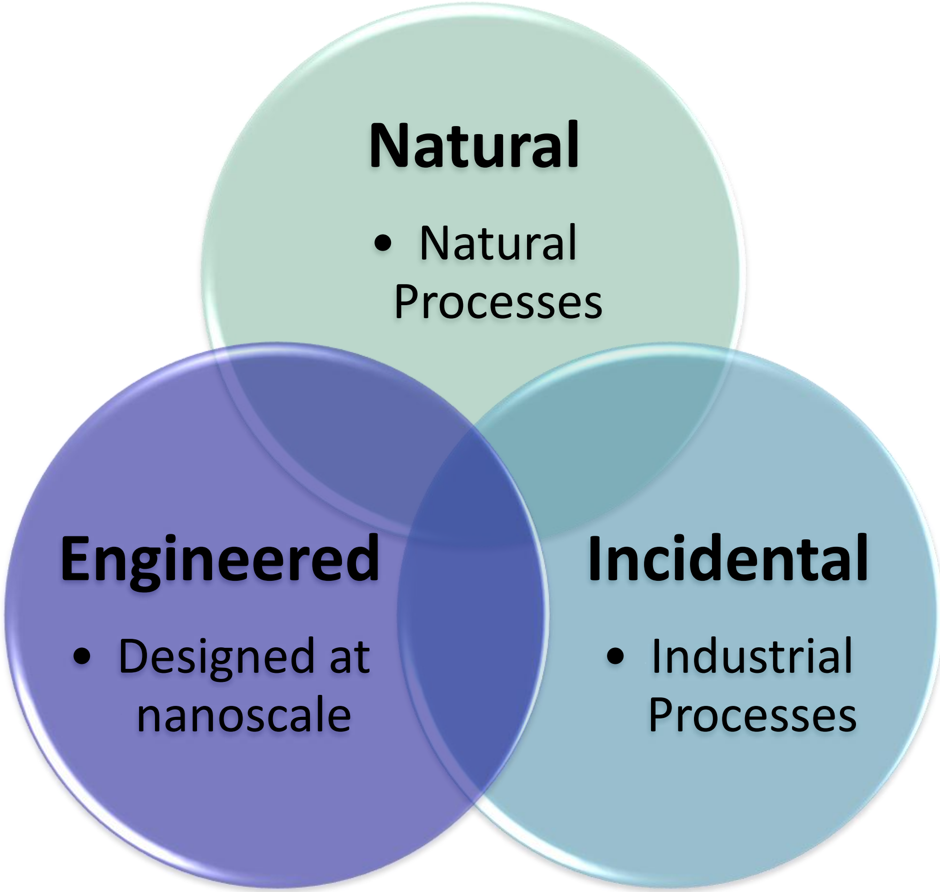
OUTLINE

- Summary of Drivers
- Usage & Regulatory Information
- Assessment Methodology
- Results & Recommendations
- Path Forward

Nanomaterials

Substances with at least one dimension between approximately 1 and 100 nanometers (nm)



Nano-Composite Coatings

Accomplishment:

Composite coatings combining nanocrystalline particles with an amorphous metal matrix have been developed that give an order of magnitude decrease in component wear, good corrosion prevention in salt environments, and enable system operation under demanding lubricant starvation requirements.

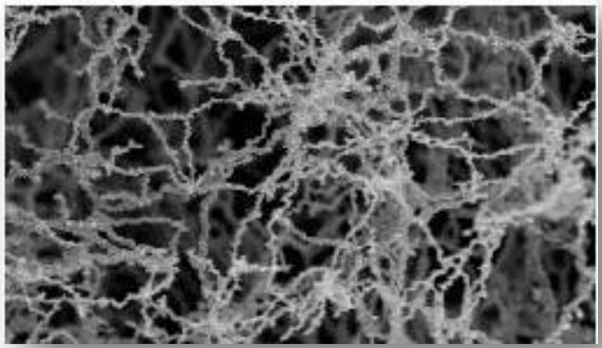
Impact:

This advancement satisfies operational requirements for endurance and reliability of F-35 aircraft. Conventional coatings are unable to satisfy the full range of operation conditions. This advanced coating is being certified for F-35 aircraft gears and is also being validated in component-level testing for gears in the RL-10 liquid rocket engine turbopump.

Nickel Nano-Strands for Aircraft

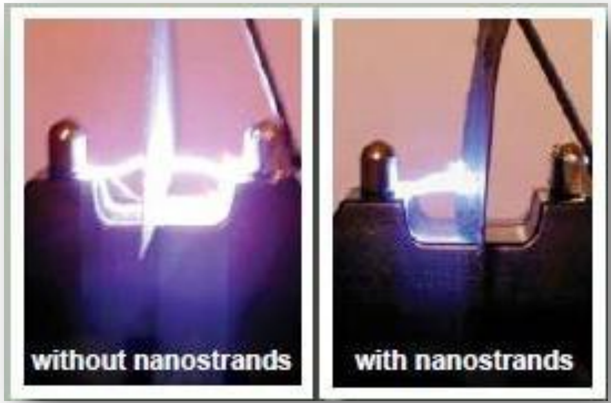
Accomplishment:

Electrically conductive structural composites, polymers, paints, adhesives and ceramics have been produced by adding nickel nanostrands that are 100-150 nanometers in diameter and up to a millimeter in length.



Impact:

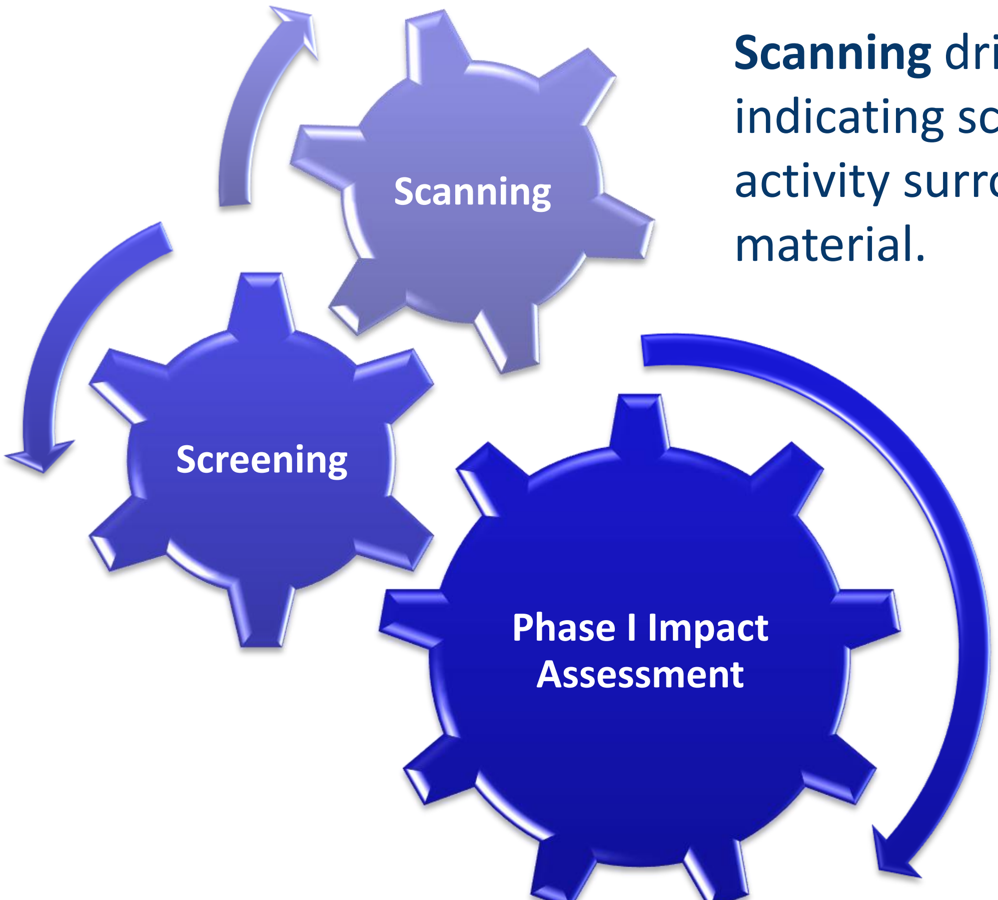
Significant protection from lightning strike damage, required for all-weather aircraft operation, has been demonstrated with nickel nanostrands. Conductive polymers using nickel nanostrands are being validated for shielding of electronic components from electromagnetic pulses, saving 150 lbs per aircraft over the current metal shielding. Electrically conductive coatings using nickel nanostrands are now fielded in other critical DoD applications.



Summary of Drivers

U.S. Federal Regulations	U.S. State Regulations	International Regulations
• U.S. Environmental Protection Agency has proposed regulation of nanomaterials through the Toxic Substances Control Act (TSCA) • With respect to statutes such as the Clean Air Act (CAA) or Clean Water Act (CWA), the USEPA maintains the authority to regulate nanomaterials as pollutants	• California has taken the lead in addressing nanomaterials as an EC, largely through voluntary reporting efforts • California and several other states have listed nanomaterials as a priority contaminant of concern	• The European Union (EU) is regulating nanomaterials under the Regulation, Evaluation, Authorization, and Restriction of Chemicals (REACH) legislation • Individual countries are also reviewing their regulatory regimes with respect to nanomaterials

Phase I Impact Assessment Methodology



Scanning drives the process by indicating scientific and regulatory activity surrounding a chemical or material.

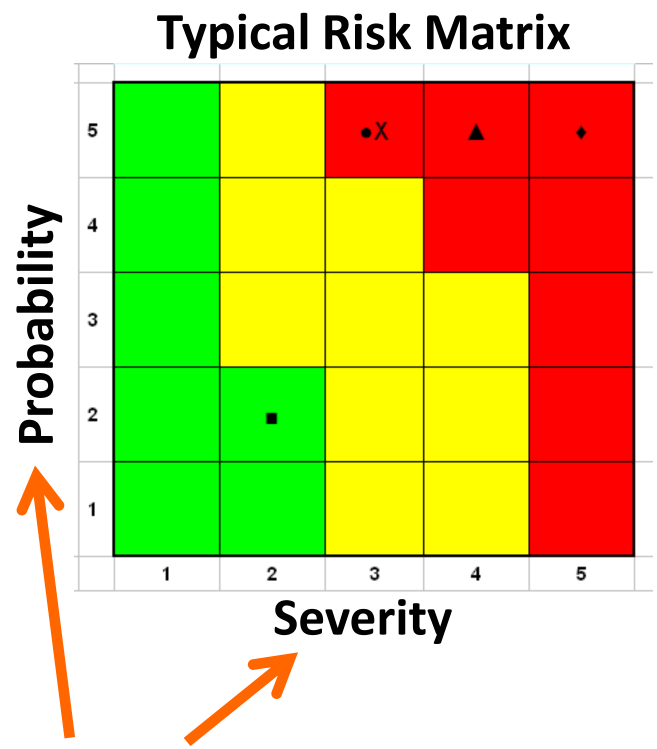
Screening focuses the process by determining whether the chemical or material is of interest to the Department of Defense (DoD).

Phase I integrates scientific/ regulatory information with DoD use information in order to assess where risk may lie.

Phase I Impact Assessment Input and Output

Subject Matter Experts (SMEs) from throughout DoD are asked questions spanning **5 functional areas**:

- Environment, Safety and Health (ESH)
- Acquisition/Research, Development, Test and Evaluation (A/RDT&E)
- Production, Operation, Maintenance and Disposal of Assets (POMD)
- Training and Readiness (T&R)
- Cleanup

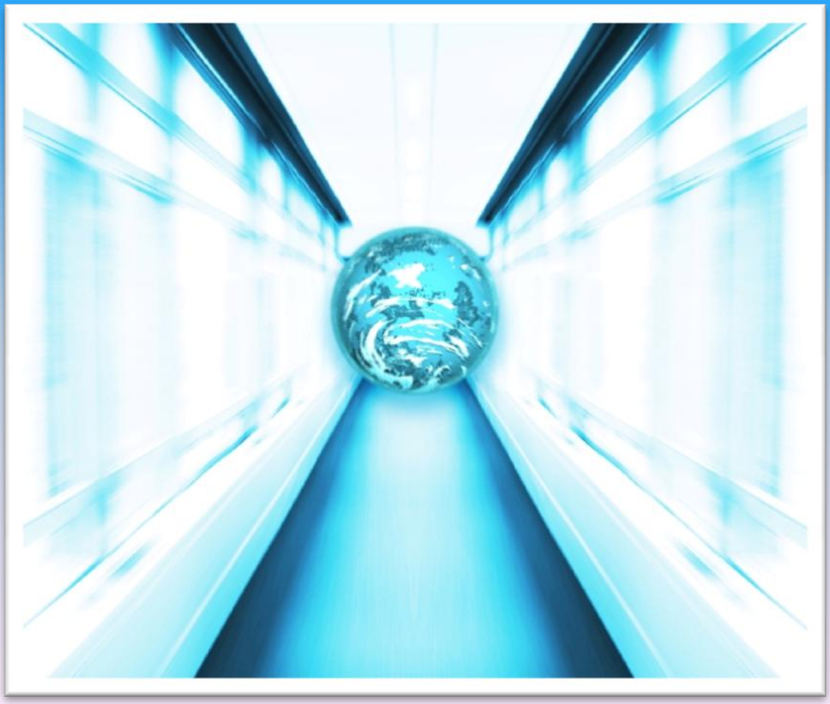


Each question is scored twice. Comments are also collected.

Dynamic:

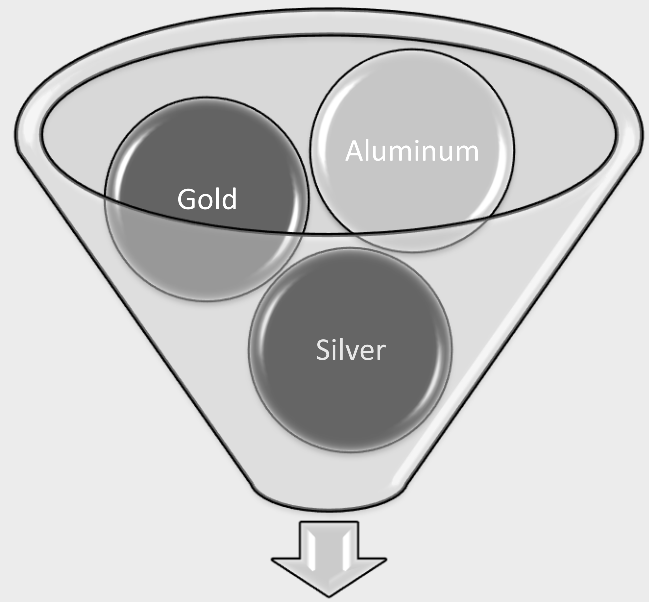
Characterized by continuous change, activity, or progress.

A dynamic scientific and regulatory climate calls for a dynamic approach to risk assessment.



Scanning

Standard Process	Modified Process
Literature, periodicals, and regulatory communication discuss one chemical, material, or small family of chemicals/materials at a time.	Literature often discusses '**nanomaterials**' as a broad category. Which ones are most prominent?



Metal-Based Nanomaterials

Screening

Standard Process	Modified Process
Search public and DoD **databases** for information about the **locations** and **quantities** of the chemical or material of interest. This determines the **magnitude** of the issue. (How widespread is use? How much is being used?)	Nanomaterial use is not currently being recorded in the standard databases. Information was collected from public and DoD **reports**. Locations and quantities were generally not available—however, **types of nanomaterials** were. ***Metals, Metal Oxides***

Phase I Impact Assessment

Standard Process	Modified Process
Questions within the assessment are generally focused around a **primary driver** (a new or changing regulation, a specific use of a chemical, a specific geographic area, etc.). The risk is assessed across **5 functional areas** to develop a clear picture of exactly where the risk lies.	For nanomaterials, there is **no single, primary driver**. 1 functional area (Cleanup) was dropped due to lack of available information. The questions within the remaining 4 functional areas were **edited to address some unique uncertainties** associated with nanomaterials.

Results

Overall Risk

Environment, Safety and Health
Training / Readiness
Acquisition / Research, Development, Testing, and Evaluation
Production, Operations, Maintenance, and Disposal of Assets

Environment, Safety and Health

E1	Human Health
E2	Occupational Health (civilian and uniformed)
E3	Ecological Health
E4	Community, Public and Worker Relations

Training / Readiness

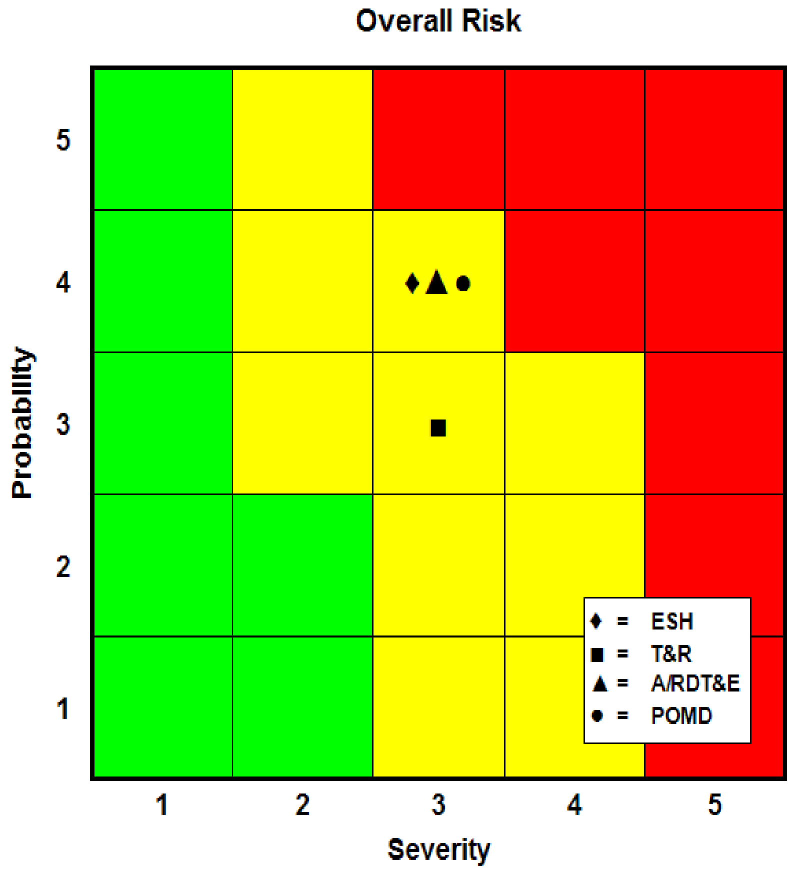
RT1	Training Activities (Activity Specific)
RT2	Training Activities (System Specific)

Acquisition / Research, Development, Testing, and Evaluation

R1	Material Laboratory and Field Scale Activities
R2	Material Labeling
R3	Cost and Schedule
R4	Material Availability

Production, Operations, Maintenance, and Disposal of Assets

O1	Infrastructure Improvements
O2	Analytical Techniques
O3	Production and Maintenance Operations
O4	Product Labeling
O5	Waste Handling, Storage, Transport, and Disposal (HST&D)
O6	Industrial Hygiene Controls

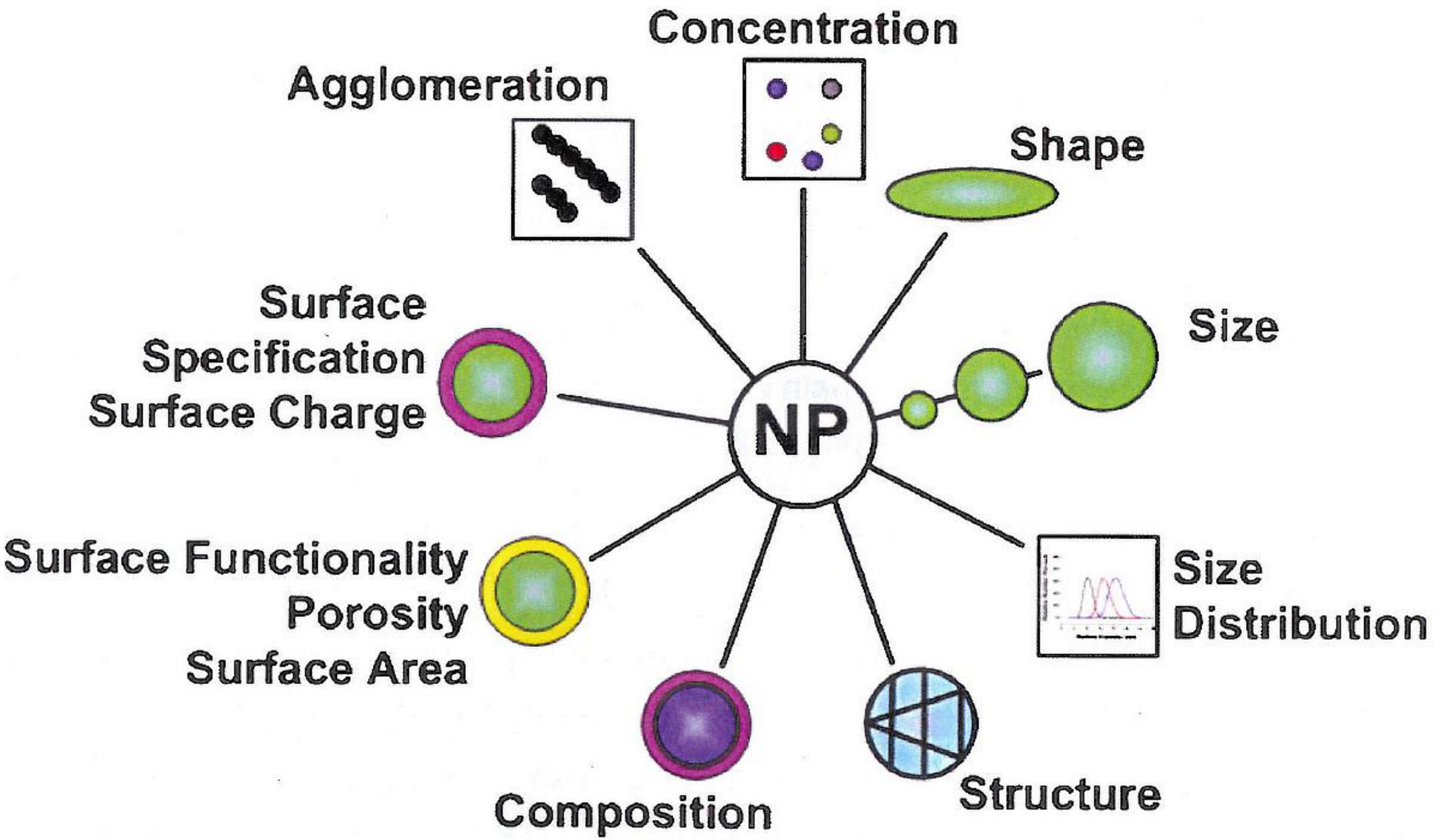


ECAS (left) and ICAT (right) results.

Obstacles Encountered

- **Unknown benefits of nanotechnology**
  (Weighing risk against an unknown reward)
- **Communication between multidisciplinary experts**
  (Speaking different technical languages)
- **Gaining access to use/location information**
- ***<u>Insufficient Analytical Capabilities</u>***
  (Complete, Integrated Characterization of Materials)

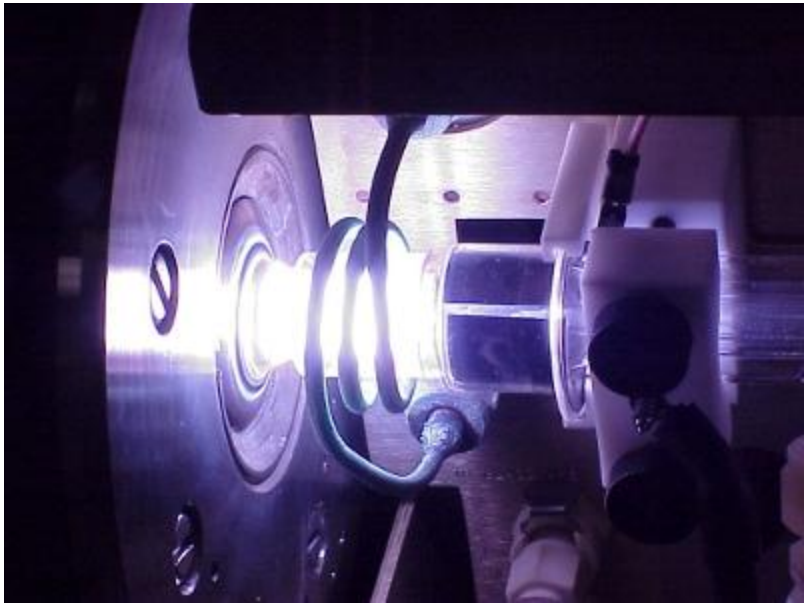
Nanomaterial Characterization



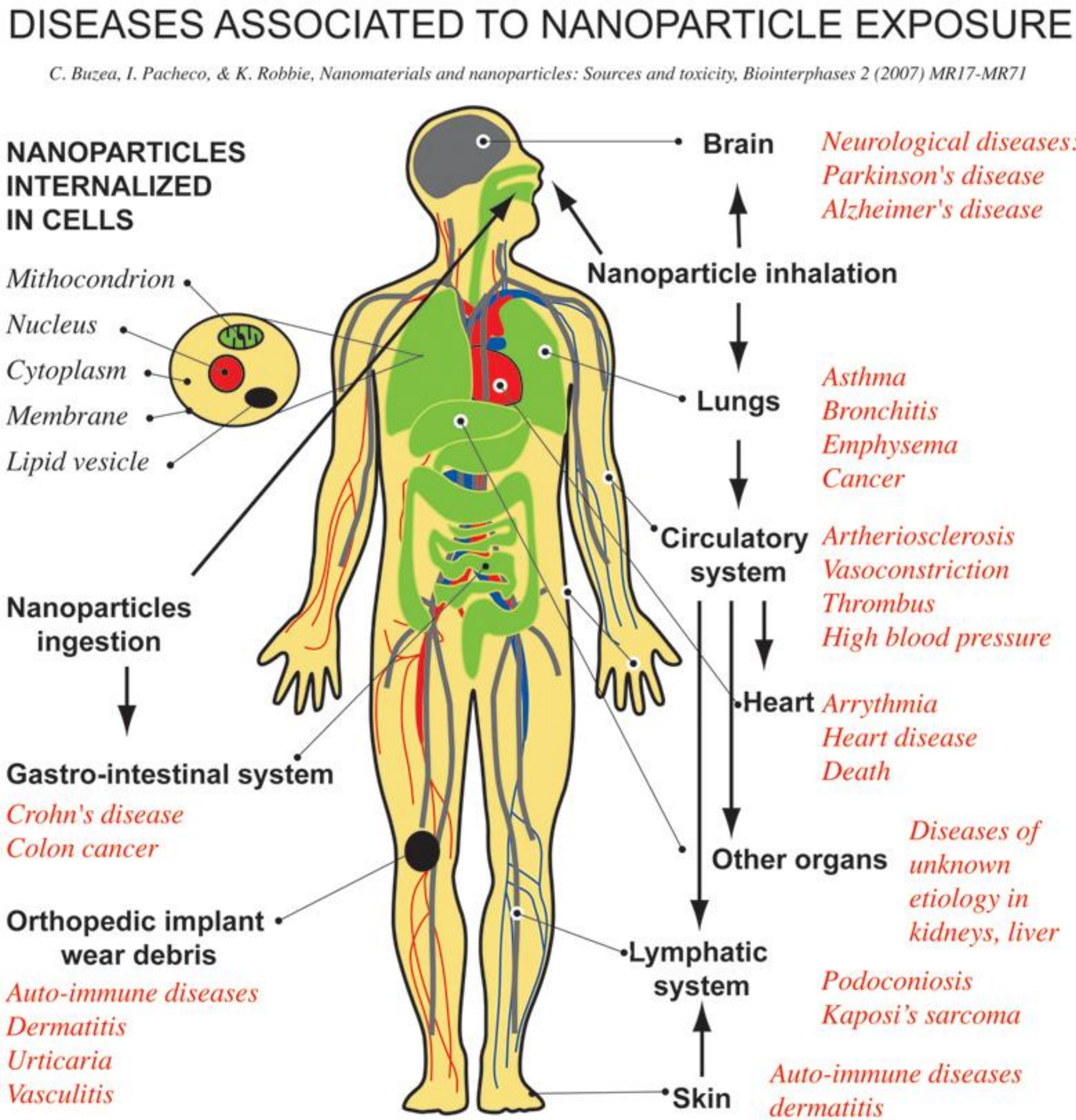
Nanomaterial Characterization

Transmission Electron Microscopy:
Particle Size and Distribution, Surface Area, Shape, Agglomeration, Structure, and Composition (*Lacking Concentration and Surface Charge*)

Inductively Couple Plasma – Mass Spectrometry:
Concentration and Composition (*Lacking Particle Size and Distribution, Surface Charge and Area, Shape, Agglomeration, and Structure*)



Nanotoxicology

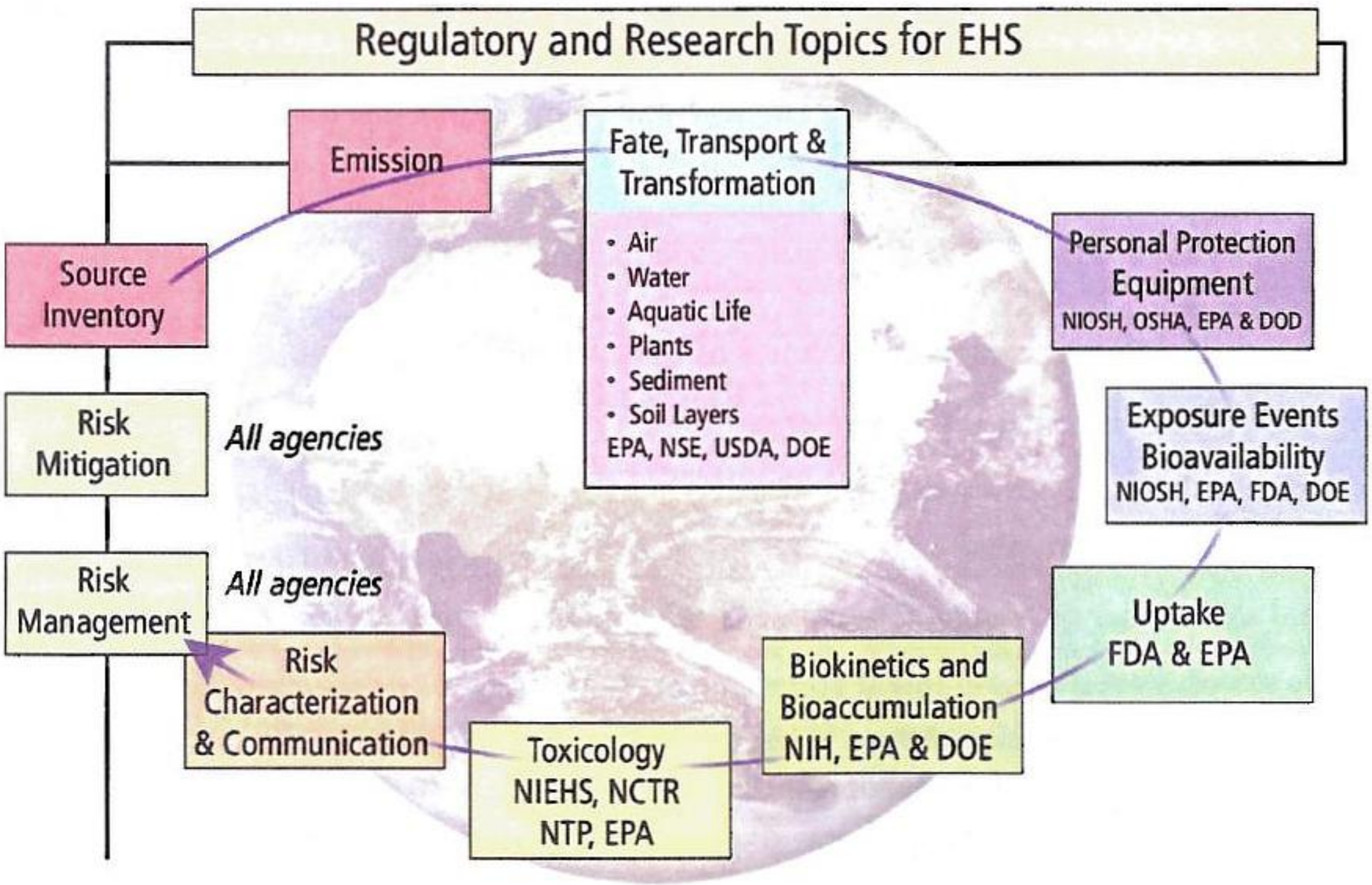


Dose Response Evaluation

- **Classical Models of Toxicity**
  - Whole System
  - Reproductive Endpoints
  - Neurological Effects
  - Immune System Effects
  - Carcinogenic Effects

- **Obstacles**
- Keeping nanoparticles separate from one another for studies (Agglomeration & Aggregation Issues)
- Variation between in vitro, in vivo, and real world exposure scenarios

Nanomaterial Life Cycle in the Environment



The Path Forward

- **Continue to develop analytical methods for nanoscale detection and monitoring**
- Begin cataloging **where** DoD is using nanomaterials, in what **quantities**, and for which **applications**.
- Begin modifying/creating databases to **store data and information** about DoD nanomaterials.
- **Engage** with the public and regulatory communities.